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AMENDMENTS TO THE CLAIMS/LISTING OF CLAIMS

Please amend claims 2, 4, 5, 14, 15, 17, 18, 20, 23, 32-34, 38, 39, 41, 43, 44 and 53-55, and cancel claims 3, 6-13, 24-31, 35, 42, 45-52 and 56 as follows. This listing of claims will replace all prior versions, and listings, of claims in this application.

1. (Original) A method of inducing differentiation of mammary epithelial cells, the method comprising administering an effective amount of galanin or a functional analog or agonist thereof to the mammary epithelial cells.

2. (Currently amended) A method of inducing differentiation of mammary epithelial cells and/or increasing milk production in a mammal, the method comprising increasing the level of galanin or a functional analog or agonist thereof in the mammary tissue of the mammal.

3. (Cancelled)

4. (Currently amended) A method as claimed in claim 2 ~~or claim 3~~, wherein the level of galanin is increased by administering to a mammal an amount of galanin or a functional analog or agonist thereof effective to induce differentiation of mammary epithelial cells and/or increase milk production in the mammal.

5. (Currently amended) A method as claimed in ~~any one of~~ claim[[s]] 1 [[to 4]], wherein the galanin or functional analog or agonist thereof is selected from the group consisting of:

a polypeptide comprising the ~~following~~ fragment[[:]] GWTLNSAGYLLGP (SEQ ID NO:1);

a human galanin polypeptide having the amino acid sequence
GWTLNSAGYLLGPHAVGNHRSFSDKNGLTS (SEQ ID NO:2) or a functional
equivalent thereof or a functional fragment thereof;

a bovine galanin polypeptide having the amino acid sequence
GWTLNSAGYLLGPHALDSHRSFQDKHGLA (SEQ ID NO:3) or a functional
equivalent thereof or a functional fragment thereof;

a porcine galanin polypeptide having the amino acid sequence
GWTLNSAGYLLGPHAIDNHRSFHDKYGLA (SEQ ID NO:4) or a functional
equivalent thereof or a functional fragment thereof;

a rat galanin polypeptide having the amino acid sequence
GWTLNSAGYLLGPHAIDNHRSFSDKHGLT (SEQ ID NO:5) or a functional
equivalent thereof or a functional fragment thereof;

a galanin analog having the amino the amino acid sequence
GWTLNSAGYLLGPHAVNHRSFSDKNGLTS (SEQ ID NO:6) or a functional
equivalent thereof or a functional fragment thereof;

a human GALP (1-60) polypeptide having the amino acid sequence
APAHRGRGGWTLNSAGYLLGPVLHLPQMGDQDGKRETALEILDWLK AIDGL
PYSHPPQPS (SEQ ID NO:11) or a functional equivalent thereof or a functional
fragment thereof;

a porcine GALP (1-60) polypeptide having the amino acid sequence
APVHRGRGGWTLNSAGYLLGPVLRHPPSRAEGGGKGKTALGILDLWKAIDG
LPYPSQLAS (SEQ ID NO:12) or a functional equivalent thereof or a functional
fragment thereof; and

a rat GALP (1-60) polypeptide having the amino acid sequence
APAHRGRGGWTLNSAGYLLGPVLHLSSKANGGRKTDSALEILDWLK AIDGL
RYSRSPRMT (SEQ ID NO:13) or a functional equivalent thereof or a functional
fragment thereof.

6-13. (Cancelled)

14. (Currently amended) A method as claimed in ~~any one of claim~~[[s]] 1 ~~[[to 4]]~~, wherein the galanin analog is selected from the group consisting of:

- (i) Galanin-(2-29) (i.e. deletion of first amino acid);
- (ii) Galanin-(3-29) (i.e. deletion of first 2 amino acids);
- (iii) Galanin-(1-15) (i.e. deletion of amino acids 16-29/30);
- (iv) Galanin-(1-16) (i.e. deletion of amino acids 17-29/30);
- (v) M40: galanin-(1-13)-Pro-Pro-Ala-Leu-Ala-Leu-Ala-amide;
- (vi) M15 (galantide): Gly-Trp-Thr-Leu-Asn-Ser-Ala-Gly-Tyr-Leu-Leu-Gly-Pro-Gln-Gin-Phe-Phe-Gly-Leu-Met-NH₂ (SEQ ID NO: 13);
- (vii) M35: galanin (1-13)-bradykinin (2-9) amide;
- (viii) M32: galanin(1-13)-neuropeptide Y(25-36) amide; and
- (ix) C7: galanin(1-13)-spantide amide.

15. (Currently amended) A method as claimed in ~~any one of claim~~[[s]] 1 ~~[[to 4]]~~, wherein the galanin analog is an agonist of the GalR2 receptor.

16. (Original) A method as claimed in claim 15, wherein the agonist of the GalR2 receptor is a GALP(1-60) polypeptide or galanin(2-16).

17. (Currently amended) A method as claimed in ~~any one of claims 1 to 3~~ claim 2, wherein the level of galanin in the mammary tissue is increased by administering to the mammal an amount of estrogen or a functional analog thereof effective to increase expression of galanin in the mammal.

18. (Currently amended) A method as claimed in ~~any one of claims 1 to 17~~ claim 2, wherein the increase in the level of galanin or a functional analog or agonist thereof is brought about in conjunction with an increase in level or activity of prolactin or an analog thereof.

19. (Original) A method as claimed in any claim 18, wherein galanin or an analog or agonist thereof is administered to the mammal in conjunction with prolactin or an analog thereof.

20. (Currently amended) A method as claimed in ~~any one of claims 1 to 19~~ **claim 2**, wherein the mammal is selected from the group consisting of primates including human beings, cows, sheep, goats, horses, dogs, cats, rabbits, guinea pigs, rats, mice or other bovine, ovine, equine, canine, feline, rodent or murine species.

21. (Original) A method of enhancing mammary development in a mammal, the method comprising increasing the level of galanin or a functional analog or agonist thereof and increasing the level of prolactin or an analog thereof.

22. (Original) A method as claimed in claim 21 which comprises administering galanin or an analog or agonist thereof in conjunction with prolactin or an analog thereof.

23. (Currently amended) A method as claimed in claim 21 ~~or claim 22~~, wherein the galanin **or functional** analog **or agonist thereof** is **selected from the group consisting of:**

a polypeptide comprising the **following** fragment[[:]] GWTLNSAGYLLGP (SEQ ID NO:1);

a human galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHAVGNHRSFSDKNGLTS (SEQ ID NO:2) or a functional equivalent thereof or a functional fragment thereof;

a bovine galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHALDSHRSFQDKHGLA (SEQ ID NO:3) or a functional equivalent thereof or a functional fragment thereof;

a porcine galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHAIDNHRSFHDKYGLA (SEQ ID NO:4) or a functional equivalent thereof or a functional fragment thereof;

a rat galanin polypeptide having the amino acid sequence
GWTLSAGYLLGPHAIDNHRFSFDKHGLT (SEQ ID NO:5) or a functional
equivalent thereof or a functional fragment thereof;

a galanin analog having the amino the amino acid sequence
GWTLSAGYLLGPHAVNHRFSFDKNGLTS (SEQ ID NO:6) or a functional
equivalent thereof or a functional fragment thereof;

a human GALP (1-60) polypeptide having the amino acid sequence
APHRGRGGWTLNSAGYLLGPVLHLPQMGDQDGKRETALEILDLWKAIDGL
PYSHPPQPS (SEQ ID NO:11) or a functional equivalent thereof or a functional
fragment thereof;

a porcine GALP (1-60) polypeptide having the amino acid sequence
APVHRGRGGWTLNSAGYLLGPVLRHPPSRAEGGGKGKTALGILDLWKAIDG
LPYQSQLAS (SEQ ID NO:12) or a functional equivalent thereof or a functional
fragment thereof; and

a rat GALP (1-60) polypeptide having the amino acid sequence
APHRGRGGWTLNSAGYLLGPVLHLSSKANGGRKTDSALEILDLWKAIDGL
RYSRSPRMT (SEQ ID NO:13) or a functional equivalent thereof or a functional
fragment thereof.

24-31. (Cancelled)

32. (Currently amended) A method as claimed in claim 21 ~~or claim 22~~,
wherein the galanin analog is selected from the group consisting of:

- (i) Galanin—(2-29) (i.e. deletion of first amino acid);
- (ii) Galanin—(3-29) (i.e. deletion of first 2 amino acids);
- (iii) Galanin-(1-15) (i.e. deletion of amino acids 16-29/30);
- (iv) Galanin-(1-16) (ie. deletion of amino acids 17-29/30);
- (v) M40: galanin-(1-13)-Pro-Pro-Ala-Leu-Ala-Leu-Ala-amide;

(vi) M15 (galantide): Gly-Trp-Thr-Leu-Asn-Ser-Ala-Gly-Tyr-Leu-Leu-Gly-Pro-Gln-Gln- Phe-Phe-Gly-Leu-Met-NH₂ (SEQ ID NO: 13);

(vii) M35: galanin (1-13)-bradykinin(2-9) amide;

(viii) M32: galanin(1-13)-neuropeptide Y(25-36) amide; and

(ix) C7: galanin(1-13)-spantide amide.

33. (Currently amended) A method as claimed in claim 21 ~~or claim 22~~, wherein the galanin analog is an agonist of the GalR2 receptor.

34. (Currently amended) A method as claimed in claim 21 ~~or claim 22~~, wherein the agonist of the GalR2 receptor is a GALP(1-60) polypeptide or galanin(2-16).

35. (Cancelled)

36. (Original) A transgenic mammal having integrated in its genome a nucleic acid construct comprising a sequence encoding galanin or an analog thereof, wherein the transgenic mammal expresses galanin or an analog thereof at an elevated level compared to an equivalent non-transgenic mammal, and wherein the level of milk production is increased in the transgenic mammal when compared to an equivalent non-transgenic mammal.

37. (Original) A transgenic mammal as claimed in claim 36, wherein the transgenic mammal is a cow, sheep, pig or goat.

38. (Currently amended) A transgenic mammal as claimed in claim 36 ~~or claim 37~~, wherein the sequence encoding galanin is selected from a cDNA sequence as shown in SEQ ID NO:14 (which encodes human galanin) or a fragment thereof, SEQ ID NO:15 or a fragment thereof (which encodes bovine galanin) and SEQ ID NO:16 or a fragment thereof (which encodes porcine galanin).

39. (Currently amended) A transgenic mammal as claimed in ~~any one of~~ claim[[s]] 36 ~~[[to 38]]~~, wherein the nucleic acid construct further comprises a mammary specific promoter operably linked to the sequence encoding galanin or an analog thereof.

40. (Original) A transgenic mammal as claimed in claim 39, wherein the mammary specific promoter is selected from the group consisting of the WAP promoter, the murine mammary tumour virus (MMTV) long terminal repeat, the new-related lipocalin (NRL) promoter, the betacasein promoter, the beta-lactoglobulin (BLG) promoter and the beta 1,4 galactosyltransferase promoter.

41. (Currently amended) A method ~~[[of]]~~ **for the treatment of a mammary hyperproliferative disease and/or** inhibiting the growth of a mammary epithelial tumour in a subject, the method comprising administering to the subject an inhibitorially effective therapeutic amount of galanin or a functional analog or agonist thereof

42. (Cancelled)

43. (Currently amended) A method as claimed in claim ~~[[42]]~~ **41**, wherein the mammary hyperproliferative disease is breast cancer.

44. (Currently amended) A method as claimed in ~~any one of~~ claim~~[[s]]~~ **41** ~~[[to 43]]~~, wherein the galanin **or functional** analog **or agonist thereof** is **selected from the group consisting of:**

a polypeptide comprising the ~~following~~ fragment~~[[:]]~~ GWTLNSAGYLLGP (SEQ ID NO:1);

a human galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHAVGNHRSFSDKNGLTS (SEQ ID NO:2) or a functional equivalent thereof or a functional fragment thereof;

a bovine galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHALDSHRSFQDKHGLA (SEQ ID NO:3) or a functional equivalent thereof or a functional fragment thereof;

a porcine galanin polypeptide having the amino acid sequence GWTLNSAGYLLGPHAIDNHRSFHDKYGLA (SEQ ID NO:4) or a functional equivalent thereof or a functional fragment thereof;

a rat galanin polypeptide having the amino acid sequence
GWTLNSAGYLLGPHAIDNHRFSFDKHGLT (SEQ ID NO:5) or a functional
equivalent thereof or a functional fragment thereof;

a galanin analog having the amino the amino acid sequence
GWTLNSAGYLLGPHAVNHRFSFDKNGLTS (SEQ ID NO:6) or a functional
equivalent thereof or a functional fragment thereof;

a human GALP (1-60) polypeptide having the amino acid sequence
APAHRGRGGWTLNSAGYLLGPVLHLPQMGDQDGKRETALEILDLWKAIDGL
PYSHPPQPS (SEQ ID NO:11) or a functional equivalent thereof or a functional
fragment thereof;

a porcine GALP (1-60) polypeptide having the amino acid sequence
APVHRGRGGWTLNSAGYLLGPVLRHPPSRAEGGGKGKTALGILDLWKAIDG
LPYPQSQLAS (SEQ ID NO:12) or a functional equivalent thereof or a functional
fragment thereof; and

a rat GALP (1-60) polypeptide having the amino acid sequence
APAHRGRGGWTLNSAGYLLGPVLHLSSKANGGRKTDSALEILDLWKAIDGL
RYSRSPRMT (SEQ ID NO:13) or a functional equivalent thereof or a functional
fragment thereof.

45-52. (Cancelled)

53. (Currently amended) A method as claimed in ~~any one of~~ claim[[s]] 41 [[to 43]], wherein the galanin analog is selected from the group consisting of:

- (i) Galanin-(2-29) (i e. deletion of first amino acid);
- (ii) Galanin-(3-29) (i.e., deletion of first 2 amino acids);
- (iii) Galanin-(1-15) (i.e. deletion of amino acids 16-29/30);
- (iv) Galanin-(1-16) (i.e. deletion of amino acids 17-29/30);
- (v) M40: galanin-(1-13)-Pro-Pro-Ala-Leu-Ala-Leu-Ala-amide;

(vi) M15 (galantide): Gly-Trp-Thr-Leu-Asn-Ser-Ala-Gly-Tyr-Leu-Leu-Gly-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-NH₂ (SEQ ID NO: 13);

(vii) M35; galanin(1-13)-bradykinin(2-9) amide;

(viii) M32: galanin (1-13)-neuropeptide Y(25-36) amide; and

(ix) C7: galanin(1-13)-spantide amide.

54. (Currently amended) A method as claimed in ~~any one of~~ claim[[s]] 41 ~~[[to 43]]~~, wherein the galanin analog is an agonist of the GalR2 receptor.

55. (Currently amended) A method as claimed in ~~any one of~~ claim[[s]] 41 ~~[[to 43]]~~, wherein the agonist of the GalR2 receptor is a GALP(1-60) polypeptide or galanin(2-16).

56. (Cancelled)